

CERTIFICATE OF MAILING
37 C.F.R. 1.8

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January 14, 2003
Date

Charles P. Landrum
Charles P. Landrum

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Yeh et al.

Serial No.: 09/878,124

Filed: June 8, 2001

For: INHIBITORS OF C-REACTIVE PROTEIN
INDUCED INFLAMMATION

Group Art Unit: 1632

Examiner: Bertoglio, Valerie E.

Atty. Dkt. No.: UTSH:249US

I. RESPONSE TO RESTRICTION REQUIREMENT DATED OCTOBER 2, 2002; AND
II. PETITION FOR EXTENSION OF TIME

Commissioner for Patents
Washington, D.C. 20231

Commissioner:

This paper is submitted in response to the Restriction Requirement dated October 2, 2002 for which the date for response was November 2, 2002.

A request for a three month extension of time to respond is included herewith along with the required fee. This three month extension will bring the due date to February 2, 2003, which is within the six-month statutory period. Should such request or fee be deficient or absent, consider this paragraph such a request and authorization to withdraw the appropriate fee under 37 C.F.R. §§ 1.16 to 1.21 from Fulbright & Jaworski L.L.P. Account No.: 50-1212/UTSH:249US.

In response to the restriction requirement, which the Examiner imposed, Applicants elect, with traverse, to prosecute claims 1-6, 14-18, 28-37, 38, and 52 with respect to ICAM-1, *i.e.*, the Group I claims. Even though Applicants have elected ICAM-1 (Group I) the restriction is improper for restricting the group of adhesion molecules into separate *inventions* (*i.e.*, ICAM-1 (Group I), VCAM (Group II) and E-selectin (Group III)). Claim 2 states "The method of claim 1, wherein the assay comprises assaying for C-reactive protein induction of the expression of an adhesion molecule." Claim 3 states "The method of claim 2, wherein the adhesion molecule is ICAM-1, VCAM, or E-selectin." Clearly, these molecules are species of one invention, *i.e.*, a method of screening including an assay for adhesion molecules. Instead, the Examiner has required that claims dependent on claim 2 be further restricted. Claim 4 states "The method of claim 2, wherein the first candidate substance inhibits C-reactive protein induced expression of the adhesion molecule." Claim 5 states "The method of claim 2, wherein the first candidate substance enhances C-reactive protein induced expression of the adhesion molecule."

Groups I, II, and III are further restricted with respect to procurement of C-reactive protein, claims 14-18; compositions comprising a candidate substance, claims 28-37; and methods of inhibiting C-reactive protein modulated inflammation and methods of screening for a modified modulator, independent claims 38 and 52, respectively.

Applicants note that 37 C.F.R. § 1.141(a) reads:

(a) Two or more independent and distinct inventions may not be claimed in one national application, *except that more than one species of an invention, not to exceed a reasonable number*, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§ 1.75) or otherwise include all the limitations of the generic claim. (emphasis added)

Applicants traverse the restriction between groups I, II, and III in regard to improper restriction based on a demonstrable unity of invention between what are more properly *species* of claim 2,

as these species are directed to adhesion molecules. The MPEP 803.02 states in part "...it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980; and *Ex Parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility." Although written in the disjunctive, instead of a Markush group, claim 3 for all intents and purposes should be viewed in light of MPEP 803.02 as sharing a common utility as a marker protein in an assay for modulators of C-reactive protein and sharing a substantial structural feature in that ICAM-1, VCAM, and E-selectin are adhesion molecules, as provided in the specification on page 4, lines 11-20. Applicants submit that the examination of ICAM-1, VCAM, and E-selectin are sufficiently few in number as to not seriously burden the Examiner.

Applicants also submit, that claim 2 should be specified as a linking claim between the species of claim 3. Applicants argue, pursuant to MPEP 809.03 and 809.04, that claim 2 is a generic claim reading on adhesion molecule, *i.e.*, a genus claim linking species claims, that links the species of adhesion molecule recited in claim 3, *i.e.*, ICAM-1, VCAM and E-selectin (group I, II, and III respectively). Where linking claims exist, a restriction requirement may be effected, specifying which claims are to be linking (MPEP 809.03). If a linking claim is allowed, the Examiner must thereafter examine species if the linking claim is generic thereto, or she must examine the claims to the nonelected inventions that are linked to the elected invention by such allowed linking claim (MPEP 809.04). Further, Applicants identify claim 6, which depends from claim 1, as a linking claim that may also be restricted to adhesion molecules. Again, Applicants respectfully request to have a reasonable number of species examined.

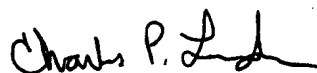
Applicants have elected ICAM-1 for prosecution on its merits and request that restriction between groups I, II, and III be withdrawn. In the least, claim 2, which is generic with respect to adhesion molecule, should be examined in addition to the elected invention and the non-elected species retained until examination of the generic claim is concluded. If the generic claim is allowed, Applicant request the withdrawal of restriction to non-elected species.

The Examiner is invited to contact the undersigned agent at (512) 536-5674 with any questions, comments or suggestions relating to the referenced patent application.

II. PETITION FOR EXTENSION OF TIME

Pursuant to 37 C.F.R. § 1.136(a), Applicant(s) petition(s) for an extension of time of three months to and including February 2, 2003, in which to respond to the Restriction Requirement dated October 2, 2002. Pursuant to 37 C.F.R. § 1.17, a check in the amount of \$465.00 is enclosed, which is the process fee for a three-month extension of time. If the check is inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski Deposit Account No. 50-1212/UTSH:249US.

Respectfully submitted,



Charles P. Landrum
Reg. No. 46,855
Agent for Applicants

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Date: January 14, 2003



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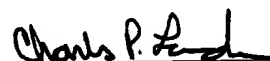
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Charles P. Landrum

Commissioner for Patents
Washington, DC 20231

Re: SN 09/878,124 entitled "INHIBITORS OF C-REACTIVE PROTEIN INDUCED INFLAMMATION" by Edward T. H. Yeh et al
Client Ref.: UTH:258.
F&J Ref.: UTSH:249US / 10105008

Dear Commissioner:

Enclosed for filing in the above-referenced patent application is:

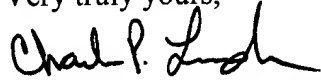
1. Response to Restriction Requirement Dated October 2, 2002;
2. A Request for an Extension of Time of three-month to and including February 2, 2003;
3. A check for \$465.00 as the fee for the extension of time; and
4. A return postcard to acknowledge receipt of these materials. Please date stamp and mail this postcard.

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Commissioner for Patents
January 14, 2003
Page 2

If the check is inadvertently omitted, or the amount is insufficient, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski L.L.P. Deposit Account No.: 50-1212/10105008/UTSH:249US.

Very truly yours,



Charles P. Landrum, Ph.D.
Reg. No. 46,855
Agent for Applicants

CPL/fb
Encl.: as noted